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K014167

E. 510(k) SUMMARY

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence
Submitter name, address, contact	Polymedica Corporation 11 State Street Woburn, MA 01801, USA (781)-933-2020 Contact Person: Patricia Collins Date prepared: 12/04/01
Device name	Proprietary name: Liberty™ Blood Glucose Monitoring System Common name: whole blood glucose test system Classification name: Glucose Test System (21 CFR 862.1345)
Predicate device	We claim substantial equivalence to the Accu-check Simplicity System marketed by Roche Diagnostics, 510(k) # K993829
Device description	The Liberty™ Blood Glucose Monitoring System consists of the following elements: test strips; a battery operated, portable, compact meter; and a control solution. Instrument Operating Principle: photometric Reagent Test Principle: glucose oxydase The Liberty™ System is based on photometric biosensor technology. The test strip is first inserted into the meter and the meter is switched on by pressing the "ON" button. A code number will appear on the display that should match the code on the vial of strips. An icon showing a flashing drop near the end of a test strip will appear on the display to prompt the user to apply a drop of blood. When a drop of blood is applied to the top of the strip at the mesh -filled target area, it flows into the membrane and starts the measurement. This is indicated on the display by a moving bar. After approximately 30 seconds, a glucose reading is displayed on the meter. The reading is stored in the meter memory with a date and time. The Liberty™ System uses a photometric test strip that includes glucose oxidase to generate a color reaction that is proportional to the concentration of glucose in the sample.
Intended use	The Liberty™ Blood Glucose System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use in the home by persons with diabetes as an aid to monitor the effectiveness of diabetes control.
Comparison to Predicate Device	The Liberty™ Blood Glucose System is substantially equivalent to the Accu-chek Simplicity System marketed by Roche Diagnostics, 510(k) K993829

SE Comparison Table, Technological Characteristics

CHARACTERISTIC	Liberty™ System	Accu-Chek Simplicity
Pre-market Notification	K014167	K993829
Marketed by	Polymedica Corporation	Roche Diagnostics
Type of Meter	Portable, battery operated, blood glucose meter	same
Glucose Measurement Technology (test strip)	Glucose oxidase chemistry; colorimetric, reflectance detection technology	same
Intended Use	Quantitative determination of glucose in blood home use, self test blood glucose monitoring by diabetics	same
Reference	Whole blood referenced	Plasma calibrated
Sample Type	Capillary whole blood	same
Sample Application	Apply blood to test strip	same
Hematocrit range	35%-55%	30%-60%
Control Solution(s)	Normal control solution, aqueous-based polymer emulsion	Normal control solution, aqueous buffered solution
Operating temperature range	59 – 95F (15 – 35C)	50 – 104F (10 to 40C)
Operating humidity range	Less than 80%	same
Dimensions	9.8 cm x 5 cm x 1.9 cm	10 cm x 5.5c m x 1.7 cm
Weight	2.1 ounces with battery	2.03 ounces without battery
Display	Liquid Crystal display	same
Results Presentation	Liquid Crystal display	same
Memory Capabilities	250 tests with time and date	30 test results with time and date
Test Start	Turn on meter, insert strip, then application of blood sample automatically starts analysis	same

CHARACTERISTIC	Liberty™ System	Accu-Chek Simplicity
Test Time	20-30 seconds	25 to 30 seconds
Power Source	Single 3-volt lithium battery	2 lithium batteries Duracell DI1/3N or 4 button batteries Varta: V13GA Ucar: A76, Panasonic LR44, Toshiba G13
Battery Life	1 year of routine usage	same
Meter coding procedure	Enter lot-specific code number from test strip bottle into meter	Code chip provided with each carton of test strips
Measurement Range	30-500 mg/dL (1.6 - 27 mmol/L)	10 – 600 mg/dL
Qualified Test Strip	Device-specific test strip	same
Qualified Control Solution	One glucose control solution	same
Accuracy Check Device	Meter automatically self-calibrates when new strip is inserted	same
Test strip storage conditions	15 – 30C (59 – 86F)	36 to 86F (2 to 30C)
Quality control procedure	Tests should be run with control solutions whenever new vial of test strips is opened or an unusual blood test result is obtained	same
Labeling instructions regarding response to unusual results	Run a quality control test, if the result is outside the acceptable QC range, contact customer service. If results are within the acceptable range, review proper testing procedure and repeat blood glucose test with a new test strip	same
Labeling instructions regarding expected results	The normal fasting adult blood glucose range for a non-diabetic is 70 – 105 mg/dL. One to two hours after meals, normal blood glucose levels should be less than 140 mg/dL. Physician will determine range that is appropriate for the patients	same
Warnings and precautions	For *in vitro* diagnostic use	same
Reagent stability	15 months	24 months

CHARACTERISTIC	Liberty™ System	Accu-Chek Simplicity
Reagent composition	Test strips: min at time of manufacture 0.016 mg Chromogen 2.3 IU Glucose oxidase, 1.0 IU Peroxidase	Test strips: qty/cm2 (minimum at time of manufacture) Glucose-dye-oxidoreductase 0.4 IU Bis-(2-hydroxyethyl)-(4-hydroxaminocyclohexa-2,5-dienylidene)-ammonium chloride 19.3 ug 2,18-Phospho-molybdic acid 328 ug Stabilizer 0.31mg Nonreactive substances 4.4 mg
	Control Solution: 0.2% sodium benzoate 10% hydrophilic synthetic polymer 0.1% Ponceau red 0.1% glucose	Control solution: Glucose Oxypyrion Germall Phosphate Buffer Solution

The non-clinical and clinical studies carried out on the Liberty™ System and the predicate device (Accu-Chek Simplicity) demonstrate that the system is substantially equivalent to the predicate device and is safe and effective for its intended use.

SE Comparison Table, Performance Characteristics

CHARACTERISTIC	Liberty™ System	Accu-Chek Simplicity
Laboratory method	Yellow Springs Instrument (YSI), HemoCue	YSI
Capillary blood study	N = 116 patients Linear regression: Y = 0.930 Correlation coefficient = 0.941 Range =35 – 470 mg/dL	N = 116 patients Linear regression: Y = 1.02 Correlation coefficient = 0.939 Range = 74 – 500 mg/dL
Consumer study: Studies conducted comparing patient capillary results with those of a whole blood glucose laboratory reference method	N = 116 different patients linear regression results y = 0.872 Correlation coefficient = 0.921 Range = 28 to 390 mg/dL	N = 116 different patients linear regression results y = 1.02 Correlation coefficient = 0.939 Range = 74 to 500 mg/dL
Precision Within-run precision (N=20 per level)	Control solution Medium Mean 163 mg/dl sd 11.3 CV < 1 % Blood Range 25 to 550 mg/dl R= 0.994 / 0.995 for 2 lots > 99 % of the 2 lots are in "A" region	Blood Range 35 to 450 mg/dl R= 0.996 > 93 % is in "A" region

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 9 2002

Ms. Patricia Collins
Director, Corporate QA
PolyMedica Pharmaceuticals, USA., Inc.
11 State Street
Woburn, MA 01801

Re: k014167
Trade/Device Name: Liberty™ Blood Glucose System, Liberty™ Blood Glucose Meter, Liberty™ Blood Glucose Strips, Liberty™ Control Solution
Regulation Number: 21 CFR 862.1345; 21 CFR 862.1660
Regulation Name: Glucose test system; Quality Control Materials
Regulatory Class: Class II; Class II.; Class I
Product Code: NBW; CGA; JJX
Dated: December 12, 2001
Received: December 19, 2001

Dear Ms. Collins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D. STATEMENT OF INDICATIONS FOR USE

Applicant: Polymedica Pharmaceuticals Inc

510(k) Number (if known): K014167

Device Name: Liberty™ Blood Glucose System, Liberty™ Blood Glucose Meter, Liberty™ Blood Glucose Strips, Liberty™ Control Solution

Indications For Use:

Liberty™ Blood Glucose System:
The Liberty™ Blood Glucose System is intended for the quantitative measurement of glucose in fresh capillary whole blood: Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home by persons with diabetes as an aid to monitor the effectiveness of diabetes control.

Liberty™ Blood Glucose Meter:
The Liberty™ Blood Glucose Meter is intended for use with Liberty™ Blood Glucose Strips for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home by persons with diabetes as an aid to monitor the effectiveness of diabetes control.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014167

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Liberty™ Blood Glucose Strips:
Liberty™ Blood Glucose Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood when used with the Liberty™ Blood Glucose Meter. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home by persons with diabetes as an aid to monitor the effectiveness of diabetes control.

Liberty™ Control Solution:
Liberty™ Control Solution is an aqueous glucose solution for use with the Liberty™ Blood Glucose System. It is used as a quality control check to verify the accuracy of the blood glucose test result. The Liberty™ Control Solution is intended for use in the validation of the performance of the Blood Glucose System by providing a test solution with a known range of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

Division Sign-Off
Division of Clinical
510(k) Number K041467

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)